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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,412	10/03/2001	Allan Asp	Pha-1626	2742

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Amersham Pharmacia Biotech, Inc.
800 Centennial Avenue
Piscataway, NJ 08855

EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,412

Applicant(s)

ASP ET AL.

Examiner

Diana Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Priority

1. With respect to the amendment of the first line of the specification introduced in the First Preliminary Amendment of paper no. 5, applicants are referred to MPEP 1893.03(c), which states that "a national stage application filed under 35 U.S.C. 371 may not claim benefit of the filing date of the international application of which it is the national stage since its filing date is the date of filing of that international application." Accordingly, the first line of the instant specification should be amended to clarify that the '783 application was the national stage of PCT/SE96/01464, and to include the proper filing date (i.e., that of the PCT application).
2. It is further noted that the status of nonprovisional parent application no. 09/068,783 should be included in the first line of the specification. Specifically, the specification should be amended to indicate that 09/068,783 is "now Patent No. 6,337,185."

Specification

3. The title of the invention is not descriptive of the invention of the pending claims. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-12 are indefinite over the recitation of the limitation "both primers" in line 6 of claim 11. There is insufficient antecedent basis for this limitation in the claim. Step (b) of claim 11 merely recites "amplification primers", with no limitation on the number of primers present; there is no recitation in the claim of two primers, a pair of primers, etc. Thus, there is insufficient antecedent basis for the limitation "both primers."

Claim 12 is indefinite over the recitation of the language "characterized in that." This language is vague and indefinite, as it is unclear as to whether this language is intended to indicate that particular further structural properties are required of the kit components, or whether the claim might encompass kits that are merely "characterized" or described in a certain manner. This rejection could be overcome by amending the claim to recite, e.g., "A kit according to claim 11, wherein the solid support is...and wherein the sequencing primers are...."

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Apple (WO92/10589; 6/92).

The claims are drawn to kits comprising a solid support, sequencing primers, and amplification primers comprising "one member of a specific binding pair, the member being of the same type for both primers." Claim 12 further requires that "the solid support is a manifold having a plurality of individual solid phase members" and that "the sequencing primers are differently labeled."

Apple teaches methods for amplifying and typing HLA DRbeta genes, and teaches kits comprising reagents that may be employed in his methods (p. 7-8; p. 45-50). Apple's kits comprise solid supports and primers which may be labeled or unlabeled (p. 7). Apple teaches the use of primer pairs wherein one or both primers are biotinylated (p. 34-37, especially p. 36, lines 17-20); Apple therefore teaches primers that are "differently labelled", as well as pairs of primers "comprising one member of a specific binding pair" wherein the member is identical on each of the two primers in the pair. With respect to claim 12, Apple discloses the use of filters and a dot blot manifold (p. 25). With respect to the recitation in the claims of the language "sequencing primers", the mere designation of primers as "sequencing primers" does not further limit the primers with respect to structure or function; any primer may be employed in some manner in a method of sequencing. It is an inherent property of the primers of Apple that they could be employed in sequencing. Thus, Apple anticipates the instant claims. It is also noted that Apple teaches that sequencing may be employed in analysis of HLA DRbeta genes (p. 7, p. 24).

8. Claim 11 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Soderland (EP 371437 A2; 6/90).

The claim is drawn to a kit comprising a solid support, sequencing primers, and amplification primers comprising "one member of a specific binding pair, the member being of the same type for both primers."

Soderland teaches methods for analysis of a nucleic acid sequence comprising PCR to produce a "DNA sample in which at least one attachment moiety has been introduced into at least one strand of specific target polynucleotide", attachment of target to a "solid matrix coated with an attachment site to which the attachment moiety or a modification thereof can bind", and determination of the sequence of the amplified target by a method such as the chain termination method (col 2, line 30-col 3, line 31). The affinity pairs used for attachment of target to solid support may include "biotin/avidin or streptavidin" and "hapten/antibody" (col 5, lines 36-45). While Soderland states that, in embodiments employing two modified primers, "The primers must in this case be modified with different attachment moieties", Soderland's teachings encompass the use of two different moieties that are "of the same type" (e.g., two different haptens with two different antibodies) (col 5, lines 1-4). Soderland teaches that sequencing primers "may be distinct from or equal to the primer used" in amplification, teaches the use of one or "two different sequencing primers", and teaches a variety of different labels for use in sequencing primers, including fluorescent labels (col 8, line 55-col 9, line 46). Soderland discloses that "Reagents for use in practising the method of invention may be packaged in kit

form", including amplification primers with "attachment moieties and the corresponding solid supports" and sequencing primers (col 10, line 52-col 11, line 15). With respect to the language "the member being of the same type for both primers", it is noted that Soderland teaches the use together of primers "of the same type", as discussed above. Furthermore, even if claim 11 were limited to primers comprising identical binding pair members, Soderland would anticipate such kits; the claim as written encompasses inclusion of any number of different primers, and is not limited to particular pairs of primers wherein both members of the pair comprise identical binding pair members.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soderland (EP 371437 A2; 6/90) in view of Landegren (WO94/11529; 5/94).

Claim 12 is drawn to kits comprising a solid support which "is a manifold having a plurality of individual solid phase members", differently labeled sequencing primers, and amplification primers comprising "one member of a specific binding pair, the member being of the same type for both primers".

Soderland teaches methods for analysis of a nucleic acid sequence comprising PCR to produce a "DNA sample in which at least one attachment moiety has been introduced into at least one strand of specific target polynucleotide", attachment of target to a "solid matrix coated with an attachment site to which the attachment moiety or a modification thereof can bind", and determination of the sequence of the amplified target by a method such as the chain termination method (col 2, line 30-col 3, line 31). The affinity pairs used for attachment of target to solid support may include "biotin/avidin or streptavidin" and "hapten/antibody" (col 5, lines 36-45). While Soderland states that, in embodiments employing two modified primers, "The primers must in this case be modified with different attachment moieties", Soderland's teachings encompass the use of two different moieties that are "of the same type" (e.g., two different haptens with two different antibodies) (col 5, lines 1-4). Soderland teaches that sequencing primers "may be distinct from or equal to the primer used" in amplification, teaches the use of one or "two different sequencing primers", and teaches a variety of different labels for use in sequencing primers, including fluorescent labels (col 8, line 55-col 9, line 46). Soderland discloses that

"Reagents for use in practising the method of invention may be packaged in kit form", including amplification primers with "attachment moieties and the corresponding solid supports" and sequencing primers (col 10, line 52-col 11, line 15).

While Soderland teaches the use in his method and kits of a variety of different solid supports (microparticles, test tube, dipsticks, filters, microtitration wells), and states that "The solid matrix can be of any format" (col 7, lines 4-20), Soderland does not disclose the use of a manifold "having a plurality of individual solid phase members" as a solid support, or teach solid phase members "adapted for cooperation with a corresponding set of receptacles", as required by the instant claim. Landegren teaches the use in nucleic acid sequencing of a solid support comprising a manifold having "a plurality of individual solid phase members adapted for cooperation with a corresponding set or sets of receptacles" (p. 3). Landegren discloses that the use of a multipronged manifold solid support permits one to obviate "several of the problems related to the use of separate solid phase elements, like paramagnetic beads or microtiter wells" (p. 2) while facilitating release and transfer of reaction products (p. 2-3). In view of the teachings of Landegren, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Soderland so as to have included in Soderland's kits the manifold solid support of Landegren. An ordinary artisan would have been motivated to have made such a modification in order to have provided practitioners with all the reagents needed for rapid, simultaneous sequencing of several samples using

small quantities of reagents, for the advantages of efficiency and cost-effectiveness.

With respect to the language "the member being of the same type for both primers", it is again noted that Soderland teaches the use together of primers "of the same type", as discussed above. Furthermore, even if claim 12 were limited to primers comprising identical binding pair members, the claimed kits would be obvious over the kits suggested by Soderland because the claim as written encompasses inclusion of any number of different primers, and is not limited to particular pairs of primers wherein both members of the pair comprise identical binding pair members.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Application/Control Number: 09/970,412
Art Unit: 1634

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Diana B. Johannsen
May 17, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600